

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT
LITIGATION

MDL No. 1592 (MLW)

This Document Relates to All Actions

**OPPOSITION OF BIOGEN IDEC MA INC. AND GENZYME CORPORATION
TO COLUMBIA UNIVERSITY'S EMERGENCY MOTION
TO SEAL AND RESTRICT ACCESS**

Dated: June 18, 2004

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
I. INTRODUCTION.....	1
II. BACKGROUND	1
III. ARGUMENT	6
A. None of the Documents Columbia Seeks to Withhold From the Public and Its Licensees Is Confidential.....	6
1. The Claims Filed As Part of Plaintiffs’ Reply Appendix Are Not Confidential.....	6
2. The Other File History Documents Are Not Confidential.....	7
B. The Pending Claims Disclosed in the Reply Appendix Should Not be Sealed Because the Public Interest in Free Access to This Material Outweighs Columbia’s Purported Interest in Secrecy.	8
C. Columbia’s Appeal to the Court’s Inherent Authority to Preserve the Integrity of Its Proceedings Is Misdirected.....	10
IV. CONCLUSION	12

TABLE OF AUTHORITIES

CASES

<i>Biogen, Inc. v. Berlex Laboratories, Inc.</i> , 113 F. Supp. 2d 77 (D. Mass. 2000), <i>aff'd in part, vacated in part</i> , 318 F.3d 1132 (Fed. Cir. 2003).....	6
<i>FTC v. Standard Finance Management Corp.</i> , 830 F.2d 404 (1st Cir. 1987).....	8, 10
<i>Falise v. America Tobacco Co.</i> , 193 F.R.D. 73 (E.D.N.Y. 2000)	7
<i>Irons & Sears v. Dann</i> , 606 F.2d 1215 (D.C. Cir. 1981).....	10
<i>In re Knight Publ'g Co.</i> , 743 F.2d 231 (4th Cir. 1984).....	7
<i>Nixon v. Warner Communications, Inc.</i> , 435 U.S. 589 (1978).....	8
<i>Texaco P.R., Inc. v. Department of Consumer Affairs</i> , 60 F.3d 867 (1st Cir. 2000).....	7
<i>Toro Co. v. White Consolidated Industrial, Inc.</i> , 199 F.3d 1295 (Fed. Cir. 1999).....	6
<i>United States v. Real Prop. known as 77 East 3rd St., New York, NY</i> , 849 F. Supp. 876 (S.D.N.Y. 1994).....	8
<i>United States v. Sampson</i> , 297 F. Supp. 2d 342 (D. Mass. 2003)	8
<i>United States v. Santiago-Lugo</i> , 904 F. Supp. 43 (D.P.R. 1995).....	12
<i>In re von Bulow</i> , 828 F.2d 94 (2d Cir. 1987).....	6
<i>Wang Laboratories, Inc. v. America Online, Inc.</i> , 197 F.3d 1377 (Fed. Cir. 1999).....	6

STATUTES AND OTHER AUTHORITIES

35 U.S.C. § 112.....	6
35 U.S.C. § 122.....	10

I. INTRODUCTION

More than two weeks after plaintiffs filed the document in question in this Court's electronic docket for the entire world to see, Columbia University ("Columbia") has filed an "emergency" motion to seal and restrict access to claims Columbia filed in 2003 in the prosecution of its U.S. Patent Application No. 08/477,159 (" '159 application"). Because of the PTO's repeated disclosures of the '159 file history, and because of Columbia's inaction on numerous occasions when it was clear that all or nearly all plaintiffs had access to the file history of the '159 application, Columbia has waived its claims of confidentiality, and the matter is moot.

Even apart from the mootness of Columbia's belated motion, Columbia has offered only the most hypothetical of reasons to rebut the presumption of public access to the document now before the Court. In fact, the presumption is further strengthened by the public interest in the transparency of patent prosecution, the potential impact of the pending application on plaintiffs' drug products, and the interests of Columbia's licensees in knowing of the claims pending in a patent application they have licensed from Columbia for valuable consideration. Accordingly, Biogen Idec MA Inc. ("Biogen") and Genzyme Corporation ("Genzyme") (collectively, "plaintiffs") oppose Columbia's "emergency" motion to seal this public document and restrict the entire file history so that it can be seen only by plaintiffs' outside counsel.

II. BACKGROUND

In the 1970s, the National Institutes of Health ("NIH") funded research by scientists at Columbia University. In 1980, Columbia filed a patent application based on that research. In 1983, a patent issued from this application, U.S. Patent No. 4,399,216 ("the '216 patent"). Columbia filed numerous continuations of its original application, receiving U.S. Patents

4,634,665 and 5,179,017 in 1987 and 1993 respectively (these three patents are referred to below as the “original Axel patents”).

In December 1993, as Columbia continued to prosecute continuations of the ’216 patent, it entered into a license agreement with plaintiff Biogen, Inc. (“Biogen”). The rights Biogen licensed included the original Axel patents and “any and all divisions, continuations and continuations-in-part based on any of the foregoing; any and all patents issued therefrom and any and all reissues or extensions thereof.” Biogen License § 1(c), Reply Mem. Supp. Joint Mot. for Prelim. Inj., Tab 1 (Court’s Docket No. 49). In February 1994, Genzyme entered into an agreement that is identical in all relevant respects. Genzyme License, Reply Mem. Supp. Joint Mot. for Prelim. Inj., Tab 2 (Court’s Docket No. 49).

On June 7, 1995, Columbia filed two continuations from the application it then had pending. One of these applications ultimately issued as the ’275 patent. The other, which remains pending to this day, was the ’159 application at issue in Columbia’s motion to seal.

The original Axel patents expired in 2000. Relying on the license provision quoted above, however, Columbia demanded royalty payments from at least some licensees based on its previously undisclosed, pending applications, including the ’159 application. Am. Compl., ¶ 4, *Immunex Corp. et al. v. Trs. of Columbia Univ.*, No. CV 03-4349 (C.D. Cal. filed Jun. 18, 2003) (Tab 1).¹ The existence of the ’159 application became public in September 2002 with the issuance of the ’275 patent, which cited the ’159 application on its face under the heading “Other Publications.”

¹ Citations to new record sources are to the Appendix to the Opposition of Biogen Idec MA, Inc. and Genzyme Corporation to Columbia University’s Emergency Motion to Seal and Restrict Access, filed herewith. Citations to materials appearing in that Appendix are either to the declaration of Claire Laporte contained therein, or to materials appearing behind a numbered tab. In the latter case, the material will be cited by title and tab number.

In October, 2002, Foley Hoag requested the file histories of the original Axel patents and the '275 patent. *See* Invoice from World Patent Servs., Inc., to James Olesen (Tab 2). What the PTO released in response to this request included the '159 application and the entire record of prosecution up to the date of the request (papers 1–34, referred to by Columbia as “2002 Documents”). *Id.* At some point unknown to Biogen and Genzyme, Amgen and Immunex also received the '159 application file history from the PTO. *See* Letter from Arthur Wineburg, Pillsbury Winthrop LLP, to DoHoang Tini Duong, Gibson, Dunn & Crutcher LLP (June 14, 2004) (Tab 3). Also, at least as early as November, 2002, in-house counsel at Biogen also received the file history. Biogen believes that the PTO may have provided a copy of it directly to Biogen.

Columbia states that, at some unspecified time, it became aware that one or more third parties had received “improper access” to the '159 application, and that at some later unspecified time, it so informed the PTO and received confirmation of the application’s confidentiality. Columbia’s declarations and memoranda carefully avoid revealing the date on which Columbia became aware that the PTO had released the file history publicly, and so it cannot be determined whether this occurred shortly after the PTO’s 2002 disclosures to plaintiffs or at some later time.

On July 15, 2003, Biogen, Genzyme, and Abbott filed their complaint in this action. The complaint made allegations concerning several events in the '159 application file history. *See* Compl. ¶¶ 22 (describing claims sought in the '159 application), 62–63 (describing claims sought and office action rejecting claim). Although these allegations made clear that plaintiffs had access to the '159 file history, Columbia made no objection to the inclusion of this information in the public record of the case. On August 21, Biogen, Genzyme, and Abbott filed

their amended complaint, which was identical in all relevant respects to the original July 15 complaint. *See* Am. Compl. (Court's Docket No. 6). Again Columbia made no objection.

On September 5, 2003, Columbia answered the amended complaint, averring that "the contents of the '159 Application and its prosecution history speak for themselves." Answer to Am. Compl., ¶ 63 (Court's Docket No. 8); *see also id.* ¶¶ 22, 64. Despite providing specific answers to allegations concerning the prosecution history of the '159 application – allegations that could only have been made by plaintiffs after reviewing the file history of the application – Columbia made no objection to the inclusion of these allegations in the amended complaint.

On September 24, 2003, Amgen and Immunex filed an amended complaint in their case against Columbia. In that complaint, they made detailed allegations concerning the '159 prosecution history. *See* Immunex, Am. Compl., ¶ 46 (Tab 1) (making allegations concerning rejection of claim 135, Columbia's arguments in response, and cancellation of claim). Again, Columbia simply answered and raised no objection to the disclosure of the prosecution history. Wyeth, Johnson & Johnson, Baxter, and Serono all included similar allegations. Columbia did not object.

In March, 2004, Columbia abruptly advised Biogen and Genzyme that it intended to terminate their licenses for non-payment of royalties purportedly due under the '275 patent. On April 7, 2004, plaintiffs requested that this Court enjoin the termination. Among other reasons, plaintiffs sought to maintain their licenses to the licensed patents and applications, and in particular the '159 application.

On May 10, 2004, counsel for Biogen and Genzyme ordered a certified copy of the '159 application from World Patent Services, Inc., an independent patent retrieval service. *See* Certified Copy Order Form (May 10, 2004) (Tab 4). In response, the PTO provided a CD-ROM.

See Photocopy of CD (Tab 5). The CD-ROM, which was the source of the reply appendix material to which Columbia objects, contained the file history documents Columbia refers to as the “2003 Documents.” In particular, in addition to the claims Columbia seeks to seal, the CD-ROM also contained a terminal disclaimer filed by Columbia on October 23, 2003, a supplemental information disclosure statement, and an amendment filed by Columbia in response to an April 23, 2003 office action. At the bottom margin of each page, the materials bore the legend: “Copy provided by USPTO from the PACR Image Database on 5-11-2004.” *See, e.g.*, Amendment of Oct. 23, 2003, from ’159 Application File History, Reply Mem. Supp. Joint Mot. for Prelim. Inj., Tab 3 (Court’s Docket No. 49).

On May 26, plaintiffs filed their reply brief in support of their motion for preliminary injunction. As further proof of the irreparable harm that would befall Biogen and Genzyme upon the termination of their licenses, plaintiffs electronically filed as an exhibit the set of then-pending claims from the ’159 application’s prosecution history, showing Columbia’s efforts to obtain claims targeting plaintiffs’ products. *See id.*

After receiving plaintiffs’ reply memorandum and appendix, Columbia wrote to plaintiffs, asserting that the ’159 application claims submitted to the Court were confidential and trade secrets. Letter from David I. Gindler, Irell & Manella LLP, to Claire Laporte, Foley Hoag LLP (May 27, 2004) (Tab 6). Plaintiffs responded immediately, indicating their disagreement with Columbia’s assertion of confidentiality and setting forth the reasons for their disagreement. Letter from Claire Laporte, Foley Hoag LLP, to David I. Gindler, Irell & Manella LLP (May 28, 2004) (Tab 7). Fifteen days after the claims had been posted onto the Court’s Internet public-access Web site in this closely-watched case, Columbia filed its “emergency” motion to seal.

III. ARGUMENT

A. None of the Documents Columbia Seeks to Withhold From the Public and Its Licensees Is Confidential.

1. The Claims Filed As Part of Plaintiffs' Reply Appendix Are Not Confidential.

Columbia asserts that the pending patent claims included in plaintiffs' reply appendix are secret. This assertion is without merit. These claims are simply another reiteration of the claims Columbia first obtained when the '216 patent issued in 1983. Thus, the purportedly secret information has been a matter of public record since the issuance of that first patent more than two decades ago. Indeed, Columbia may only pursue claims that are described in and enabled by the specification. 35 U.S.C. § 112; *see Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999); *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1383 (Fed. Cir. 1999); *Biogen, Inc. v. Berlex Labs., Inc.*, 113 F. Supp. 2d 77, 96 (D. Mass. 2000), *aff'd in part, vacated in part*, 318 F.3d 1132 (Fed. Cir. 2003). The specification entered the public domain in 1983 when the '216 patent issued.

Columbia also waived and rendered moot its claim of confidentiality when it failed to take any practical measures to have the claims withdrawn from the Internet for more than two weeks following their submission to the Court. During that time, Columbia wrote to plaintiffs' counsel (and received an immediate negative response) but did not, as far as the record reflects, call the clerk, write a letter to the Court, bring a prompt emergency motion, or take any other steps to have the material withdrawn from the World Wide Web. *See In re von Bulow*, 828 F.2d 94, 103 (2d Cir. 1987) (refusing to seal information already disclosed to the public and noting that "[t]he cat is let out of the bag").²

² Amgen's recent filing attaching correspondence from Columbia's patent counsel further demonstrates the utter speciousness of its claim of confidentiality. In that correspondence, Columbia states that the pending claims "are

2. The Other File History Documents Are Not Confidential.

Columbia also claims confidentiality in the other documents disclosed by the PTO but not filed in plaintiffs' reply appendix. As far as plaintiffs' counsel have been able to determine, the PTO has freely disclosed the '159 file history. Given these disclosures – and plaintiffs consider it very likely that there were many additional disclosures that the pending investigation will uncover – the PTO placed the '159 file history in the public domain. *See Texaco P.R., Inc. v. Dep't of Consumer Affairs*, 60 F.3d 867, 883 (1st Cir. 2000); *see also Falise v. Am. Tobacco Co.*, 193 F.R.D. 73, 74 (E.D.N.Y. 2000) (noting that “any policy bases for maintaining the confidentiality of the documents in question have been eviscerated by their widespread disclosure”).

As with the claims, Columbia waived and rendered moot its claim of confidentiality by its acquiescence in and complete inaction in the face of the PTO's disclosures of the '159 file history and plaintiffs' references to the file history in their complaints. It was obvious to Columbia at least by July 2003, when Biogen, Genzyme, and Abbott filed their complaint, that the PTO had released the '159 file history. Instead of objecting at that time, Columbia simply answered the complaint. Over the following months, numerous other parties – Amgen, Wyeth, Baxter, Johnson & Johnson, and Serono – filed pleadings similarly relying on the '159 file history in support of their allegations of inequitable conduct. In each case, Columbia answered the complaint but made no objection either to the party's having obtained the file history or to the disclosure of the file history in the party's pleading. This Court should deny Columbia's motion in view of Columbia's complete inaction in the face of the PTO's dissemination of the '159 file history. *See In re Knight Publ'g Co.*, 743 F.2d 231, 235 n.1 (4th Cir. 1984) (a motion

not being treated as confidential with respect to licensees such as Immunex.” *See Amgen Inc.'s and Immunex Corporation's Opposition to Columbia University's Motion to Restrict Access to the '159 Application File*, Ex. B.

to seal may be mooted if documents have been in the public record); *United States v. Real Prop. known as 77 East 3rd St., New York, NY*, 849 F. Supp. 876, 880 (S.D.N.Y. 1994) (newspaper's access to disputed documents mooted motion to seal).

B. The Pending Claims Disclosed in the Reply Appendix Should Not be Sealed Because the Public Interest in Free Access to This Material Outweighs Columbia's Purported Interest in Secrecy.

Columbia cannot rebut the common law presumption that the public has a right of access to judicial records and documents such as the claims filed as part of plaintiffs' reply appendix. *See Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 (1978); *FTC v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 408 (1st Cir. 1987); *United States v. Sampson*, 297 F. Supp. 2d 342, 345 (D. Mass. 2003). Columbia bears the burden of showing that its private interest in secrecy outweighs the public right of access to the information. *See FTC*, 830 F.2d at 410–11; *see also Nixon*, 435 U.S. at 602. This burden becomes even weightier if the litigation is of significant public concern, as it plainly is here. *See FTC*, 830 F.2d at 412.

Columbia has advanced two principal arguments in support of its contention that the claims should be sealed and unavailable to the public. Neither provides a valid rationale for keeping the public in the dark. The first is that Columbia will suffer “significant competitive harms if the Court allows its confidential information to remain in the public domain.” Columbia's Initial Memorandum (“Mem.”) at 7. Columbia argues that it derives a “significant advantage” (in relation to whom or what is unclear) “in its attempts to license the ’159 application” when the property it seeks to license is kept secret. *Id.* at 9. Nowhere does Columbia explain why a potential licensee would be more likely to license claims it cannot examine than those it can. Indeed, it is difficult to imagine any biotechnology company that would be willing to license intellectual property of completely unknown scope (and as to which the prosecution history is also hidden, preventing the potential licensee from determining

whether flaws in the prosecution render the unknown claims invalid or unenforceable). Thus, Columbia must really be arguing that it can more readily force its current licensees to knuckle under, pay up, and abandon their challenges to the '275 patent if secret claims in the '159 application are also looming over them as a threatening unknown.

Columbia overlooks plaintiffs' right under the license agreements to know the content of the '159 claims. By the express terms of the licenses, "Licensed Patent Rights" include not only issued patents, but continuation applications such as the '159 application. "Licensed Products" are "products ... the manufacture, use or sale of which is covered by a claim of Licensed Patent Rights." *See* Biogen License, Genzyme License ¶¶ 1(c) and (d), Reply Mem. Supp. Joint Mot. for Prelim. Inj., Tabs 1 & 2 (Court's Docket No. 49). Columbia cannot reasonably argue that its licensees are not entitled to know what they have licensed. If the licensees cannot determine the scope of pending claims (which requires examining both the pending claims and the file history), how can they perform any of their obligations under their license agreements? Without knowing this information, how can a licensee determine when or whether to exercise its right to terminate the license? *See* Biogen License, Genzyme License, ¶5(c).³

Columbia's second argument is that 35 U.S.C. § 122(a) provides for the confidentiality of pending patent applications, and that this provision reflects a paramount public policy of maintaining the confidentiality of file histories. In fact, however, more recent legislation in the area has reflected Congress' policy of allowing broad public access to such information. *See*

³ As discussed above, Columbia did demand that certain of its licensees pay royalties on undisclosed pending applications. Eventually recognizing that such demands might constitute patent misuse, Columbia recently disclaimed royalties on pending applications. *See* Letter from Michael J. Cleare, Executive Director, Science & Technology Ventures, Columbia University, to Biogen, Inc. (Mar. 9, 2004) (Tab 8). Genzyme received an identical letter. Letter from Michael J. Cleare to Genzyme Corporation (Tab 9).

§ 122(b).⁴ The '159 application is “grandfathered” into § 122(a) only by virtue of Columbia’s dilatory prosecution tactics. Further, while there are sometimes compelling reasons to keep pending applications secret, in order to protect trade secrets, such a rationale is wholly inapplicable when the pending application is a continuation of a patent first published in 1983.

Weighing heavily against Columbia’s private interest in secrecy is the public’s substantial interest in disclosure. This litigation presents the question whether a fundamental technology that resulted from taxpayer-funded research in the 1970s is now rightfully in the public domain. The case is one of great importance, and the '159 application figures in it significantly. The various plaintiffs use transformed Chinese Hamster Ovary cells to produce dozens of recombinant drugs directed at multiple sclerosis, lysosomal storage disorders, cancer, hemophilia, psoriasis, and other diseases. All of these drugs could be affected by the issuance of the '159 application as a patent. The public importance of the case strengthens the presumption of public access. *See FTC*, 830 F.2d at 412 (because litigation concerned alleged deceptive trade practices and widespread consumer losses, the “threshold showing required for impoundment” was “correspondingly elevated”).

C. Columbia’s Appeal to the Court’s Inherent Authority to Preserve the Integrity of Its Proceedings Is Misdirected.

As is apparent from its supplemental brief, Columbia has correctly abandoned its reliance on Federal Rule of Civil Procedure 26(c)(7) as a source of authority for its request that plaintiffs’ counsel maintain the '159 file history on an “attorneys’ eyes only” basis. Instead, Columbia now argues as a fallback that the Court should so order as a matter of its “inherent authority to

⁴ Columbia cites *Irons & Sears v. Dann*, 606 F.2d 1215, 1221 (D.C. Cir. 1981), a case suggesting, in alarmist fashion, that applicants would be “deterred” from filing applications if they could be disclosed to competitors. Of course, the ever-increasing number of applications have not abated since § 122(b) was enacted, providing routinely for publication of pending applications.

preserve the integrity of its judicial proceedings and to enforce the applicable rules of professional responsibility.” Columbia’s Supplemental Memorandum at 1 (Court’s Docket No. 70) (“Supp. Mem.”).

If any party’s conduct threatens the integrity of these proceedings, it is Columbia’s. The ’159 patent application is a central issue in this litigation. The interaction between its prosecution and the prosecution of the ’275 patent forms an important part of plaintiffs’ allegations of inequitable conduct and prosecution laches. Its pendency also strongly supports plaintiffs’ motion for a preliminary injunction against termination of their licenses.

Notwithstanding its importance to the case and to plaintiffs’ motion for preliminary injunction, Columbia stubbornly refused to make the ’159 file history available to the Court or the parties, even upon specific Rule 34 requests and numerous letters beginning in November, 2003. *See* Plaintiffs’ First Set of Reqs. for Prod. of Docs., Reqs. 2, 12 (Tab 10); Letter from Claire Laporte, Foley Hoag LLP, to David Gindler, Irell & Manella LLP (June 4, 2004) (Tab 11); Letter from Claire Laporte, Foley Hoag LLP, to David Gindler, Irell & Manella LLP (June 10, 2004) (Tab 12). Even while refusing to produce the ’159 file history, Columbia misleadingly sought to downplay its significance to the preliminary injunction, stating, “[p]laintiffs identify no harm, let alone irreparable harm from the loss of ... the ’159 application.” *See* Def.’s Mem. Opp’n Mot. for Prelim. Inj. (Court’s Docket No. 46) at 13. Columbia also misleadingly denied that the subject matter and claims of the ’159 application were similar to the subject matter and claims of the ’275 patent. *Compare* Am. Compl., ¶¶ 62, 63, 65 (Court’s Docket No. 6), *with* Answer ¶¶ 62, 63, 65 (Court’s Docket No. 8); *compare* ’159 application claim 154, Reply Mem. Supp. Joint Mot. for Prelim. Inj., Tab 3 (Court’s Docket No. 49), *with* ’275 claim 15.

By contrast, plaintiffs have done nothing improper in receiving access, through the PTO's disclosures, to material that Columbia wrongfully withheld from them. Columbia has no basis whatsoever for its reckless assertion that counsel for Biogen and Genzyme "use[d] methods of obtaining evidence that violate[d] the legal rights of [a third person]" or violated the Massachusetts Rules of Professional Conduct, particularly given the destruction of confidentiality inherent in the PTO's multiple disclosures of the '159 file history.⁵

IV. CONCLUSION

Because the submitted excerpt from the '159 application's prosecution history is not confidential, and because Columbia has not rebutted the strong presumption of public access to judicial documents, this Court should deny Columbia's motion.

Dated: June 18, 2004

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⁵ The only case Columbia cites in support of its accusations concerning the violation of Columbia's legal rights is *United States v. Santiago-Lugo*, 904 F. Supp. 43, 44-45 (D.P.R. 1995). That case is wholly irrelevant because it involves the abuse of civil subpoena power to gain criminal discovery.